DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

August 23, 2013

Robert K. Larsen
Cao Group, Inc.
4628 West Skyhawk Drive
West Jordan, Utah 84084

Re: K123443
Trade/Device Name: Precise SHP Diode Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: August 13, 2013
Received: August 20, 2013

Dear Mr. Larsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number : K123443

Device Name: Precise SHP Diode Laser

Indications For Use:

The Precise SHP Diode Laser is indicated for dentistry and oral soft tissue procedures of:

1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue including abscess treatment, contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue.
2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

Prescription Use X **AND/OR** Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

## Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.08.23 14:44:06 -04'00'
(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K123443

# 510(k) Summary of Safety and Effectiveness

CAO Group, Inc.
4628 West Skyhawk Drive
West Jordan, UT 84084
Tel: 801-256-9282 Fax: 801-256-9287

Prepared By: Robert K. Larsen,
Preparation Date: November 5, 2012

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**Device Name:**

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|---|---|
| Trade Name: | Precise SHP Diode Laser |
| Common Name: | Soft Tissue Diode Laser |
| Product Classification: | Powered Laser Surgical Instrument |

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**Legally Marketed Predicate Devices for Substantial Equivalence:**

Precise SHP Diode Laser, manufactured by CAO Group, Inc. (K113472)

Pilot Diode Laser, manufactured by CAO Group, Inc. (K100143)

ezlase, manufactured by Biolase, Inc. (K082938)

**Rationale for Substantial Equivalence:**

The aforementioned devices share similar indications for use with the present device for excision, incision, ablation, photocoagulation, and infrared heating of tissue for temporary pain relief on soft tissue for a variety of procedures in dentistry. These devices also share an indication for a light source to activate tooth whitening materials and assist in tooth whitening procedures. The predicate devices and submitted device share similar design features including wavelength, operating controls, and laser delivery method. The devices share similar methods of control systems, safety features, and performance monitoring. The devices share similar performance specifications including power output and energy type.

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**Description of Submitted Device:**

The Precise SHP Diode Laser is a device for delivering laser energy to human soft tissue for a variety of surgical procedures and treatments. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 20nm for a maximum of 3 watts of energy output. The laser energy is delivered to surgical site by means of

an optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The device features some user definable settings, including a switchable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options.

The working end of the delivery fiber is contained within a metal handpiece with a disposable single-use tip. This handpiece system is incorporated into the device. The activation of the working beam diodes is completed by use of a foot-actuated switch.

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**Intended Uses of the Submitted Device:**

The Precise SHP Diode Laser is indicated for dentistry and oral soft tissue procedures of:

1) The removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue including abscess treatment, contouring, curettage, sulcular debridement, pulpotomy, frenectomy, gingivectomy, troughing, and removal of inflamed edematous tissue.
2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions;
3) Light activation of bleaching materials for teeth whitening and laser-assisted whitening/bleaching of teeth.

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**Technological Characteristics and Substantial Equivalence:**

The Precise SHP Diode Laser is a device for delivering laser energy to human soft tissue for a variety of surgical procedures and treatments. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ± 20nm for a maximum of 3 watts of energy output. The laser energy is delivered to surgical site by means of an optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The device features some user definable settings, including a switchable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery options.

The working end of the delivery fiber is contained within a metal handpiece with a disposable single-use tip. This handpiece system is incorporated into the device. The activation of the working beam diodes is completed by use of a foot-actuated switch.

The Pilot Diode Laser uses solid state diodes to generate laser energy in the 810nm range. This system uses a fiber delivery system to transmit laser energy to the treatment site. The system also features a 630nm aiming beam and features controls that allow for adjusting the

output of the working beam, and switching between a continuous or pulsed-mode laser emissions. The maximum output of the working beam is 9 watts.

The ezlase uses solid state diodes to generate laser energy in the 940nm range. This system uses a fiber delivery system to transmit laser energy to the treatment site. The system also features a 630nm aiming beam and features controls that allow for adjusting the output of the working beam, and switching between a continuous or pulsed-mode laser emissions. The maximum output of the working beam is 7 watts.

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**Conformity to Standards:**

The Precise SHP Diode Laser is designed to comply with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated June 24, 2007. The device also complies with the recognized standards of IEC 60601-2-22 Edition 3 and IEC 60825-1 Edition 2. The device is designed in compliance to the entirety of IEC 60601-1: 3rd Edition, IEC 60601-1-2, IEC 60601-1-4, and IEC 60601-1-6.

## Performance Data

Bench testing on an evaluation sample of the current device revealed that the device met the design criteria for essential performance, and satisfied the performance requirements indicated in 21 CFR 1010 and 21 CFR 1040. Device outputs were within performance requirements and all safety features and functions were operating correctly.

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## Conclusion

The Precise SHP Diode Laser is substantially equivalent to the listed predicate devices without raising any new issues of safety or effectiveness. This device shares similar intended uses, operating principles, design features, and similar functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.